DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration

[Docket No. 03D–0197]

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Certifier R. DESMo.

Guidance for Industry on Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate—Labeling Enforcement Policy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate—Labeling Enforcement Policy." This guidance discusses how FDA plans to exercise its enforcement discretion after September 1, 2002, with regard to drug products whose labeling does not use the established names for ensulizole, hypromellose, meradimate, octinoxate, and octisalate.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http:/

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/www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Wayne Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is announcing the availability of a guidance for industry entitled "Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate—Labeling Enforcement Policy." This guidance explains that the agency intends to exercise enforcement discretion by not initiating any enforcement action, until September 1, 2003, based on a firm's failure to bring its products' labeling into compliance with the United State Pharmacopeia (USP) monograph title changes for ensulizole, hypromellose, meradimate, octinoxate, and octisalate, as required by section 502(e)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(e)(1)(A)(i)).

As explained in detail in the guidance, a series of events has lead to the development of the guidance. These events include USP monograph title changes, changes to the FDA's monograph for over-the-counter (OTC) sunscreen drug products, and the receipt of two petitions regarding these changes and their effective date (September 1, 2002).

We are issuing this level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this issue. It does not create or confer any rights for or on any person and does not operate to bind

FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 5/19/03
May 19, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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